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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,160	01/14/2002	Rima Zoorob	1721-46	5277

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,160	ZOOROB ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The instant application has been transferred from Examiner Alexander Spiegler to Examiner Cynthia Wilder of Art Unit 1637. All future correspondence should be addressed to Examiner Cynthia Wilder whose contact information appears at the end of this Office Action.

Election/Restrictions

2. Applicant's election with traverse of Group V, claims 1-10, and SEQ ID NO: 5 in the reply filed on November 23, 2004 is acknowledged. The traversal is on the ground(s) that That the Examiner has not established by citation of an allegedly novelty-destroying prior art that the subject matter of claims do not share a common or corresponding special technical feature. Applicant argues that while the structure of the claimed subject matter may be different, as indicated by the Examiner on page 3 of the Office action dated August 25, 2004, the difference in structure alone is not believed to define separately patentable subject matter under the PCT Rules. Applicant asserts that the Examiner is either requested to establish, by citation of prior art that the claimed subject matter fails to a corresponding special technical feature, or withdraw the restriction requirement and examine all of the claimed subject matter.

Applicant's arguments have been considered but are not found persuasive for the reasons that follow: In response to Applicant's arguments that a difference in structure alone is not enough to define separately patentable subject matter, it is noted that the expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). MPEP 1850 states that lack of unity of invention may be directly evident "*a*

priori," that is, before considering the claims in relation to any prior art, *or* may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. In this case, lack of unity of invention is directly evident because the broadest first invention, namely, nucleic acid molecules isolated from their natural environment comprises a list of genes sequences which differ in structure, as evident by the different sequences recited in SEQ ID NOS: 1-8, and function one from the other. Moreso, the different genes as recited in the claims encode different proteins and is capable of functioning irrespective of each other. The different isolated nucleic acid sequences contain non-overlapping subject matter. The claims do not define a "corresponding special technical feature" which links the invention together. Therefore, requirement is still deemed proper and is therefore made FINAL. Claims 1-10 have been canceled. Claims 11-19 have been added. Claims 11-19 as they relate to SEQ ID NO: 5 are discussed in this Office action. The isolated nucleic acid sequences recited as SEQ ID NOS: 1-4, 6-8, 45 and 46 have been withdrawn from consideration as being drawn to a non-elected invention.

Information Disclosure Statement

3. The information disclosure statement filed January 14, 2002 is acknowledged and has been entered. However, copies of the documents cited therein are not in the instant application. The Examiner is making efforts to locate these references. Resubmission of these documents, if possible by Applicant would facilitate their consideration and would be greatly appreciated by the Examiner. A signed copy of the 1449 will be mailed as soon as the examiner obtains copies of the references. The Examiner regrets any inadvertent inconveniences.

Claim Rejections - 35 USC § 101/112

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 11-19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and/or credible utility, or, in the alternative, a well-established utility. The claimed invention is drawn nucleic acid molecules, isolated from the their natural environment, useful in a genotyping method enabling viro-induced diseases resistant chickens to be controlled, characterized in that they have nucleic acid sequences of C121 gene (sequence of figure 5 (SEQ ID NO: 5). The claims are also directed to a method and kit for genotyping using the nucleic acid molecule comprising the sequence of figure 5 (C121 gene). The instant application does not disclose a connection between the nucleic acid molecule comprising the sequence of SEQ ID NO: 5 and any method of genotyping or controlling viro-induced disease resistant chickens. The sequence as recited in figure 5 comprising the c121 gene is only mention in the specification at page 3. Nowhere in the specification is there any demonstration of the applicability of the gene sequence as recited in SEQ ID NO: 5 in any method or process. In the instant application, additional research would be necessary to establish substantial utility of a nucleic acid molecule comprising SEQ ID NO: 5 based on the lack of information in the specification. In order for an isolated nucleic acid to be useful for diagnosis of a disease or condition, thee must be a well-established or disclosed correlation or relation between the claimed isolated nucleic acid and a disease or disorders. Isolation of a gene sequence alone is not sufficient for establishing a utility in a diagnosis of a disease in the absence of some information regarding a correlative or causal relationship between the expression of

claimed nucleic acid and the disease. If a molecule is to be used as a surrogate for a disease state, some disease must be identified in some way with the molecule. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consist of its potential role as an object of use-testing" *Brenner*, 148 USPQ at 696. The disclosure does not present a specific or substantial utility that would support the requirements of 35 USC 101. The utility is not specific because a lot of different nucleic acids are expressed in farmed birds, as indicated by the different sequences recited in the claims. Thus, the instant invention does not disclose a specific, or substantial or readily apparent utility under 35 USC 101 for the instant invention.

6. Claims 11-19 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The discussion in the rejection under 35 USC 101 is incorporated here.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 11-19 are indefinite and confusing because the claims are generally narrative, failing to conform to current U.S. practice. They appear to be a literal translation into English

from a foreign document and are replete with grammatical and idiomatic errors. For example, the claims are confusing at "characterised in that" because it cannot be determined how the claimed scope is affected. It is suggested that typical U.S. claim language be substituted, such as e.g., "wherein". Likewise the claims are confusing, for example, in claim 17 for the limitation "originating from the animal" or "being elaborated from" because it cannot be determined how the claimed scope is affected. It is suggested that typical U.S. claim language be substituted, such as e.g., "isolated from". Clarification is required.

(b) Claim 12 is indefinite at "a part specific and discriminating for a given gene of the B and Rfp-Y systems" because it cannot be determined what constitutes "a part specific and discriminating for a given gene". Likewise, the claim lacks proper antecedent basis for "the B and Rfp-Y systems" because the claim 11 from which it depends does not recite any B or Rfp-Y systems. Clarification is required.

(c) Claims 13 and 15 lack proper antecedent basis for "the polymorphic region of the system of the major histocompatibility complex" because the claim 12 from which it depends does not recite any "polymorphic region" or any "major histocompatibility complex". It is suggested amending the claim such that the claims languages agree.

(d) Claim 17 lacks antecedent basis for "the animal" and "the said birds" because no previous limitation recite any "birds" but recites "domestic fowl". It is suggested amending the claims such that the claim language agrees.

(e) Claims 17 and 18 are confusing overall and lacks a final process step that clearly relates back to the preamble. The claims are drawn to a method of genotyping domestic fowl and enabling animals resistant to viro-induced diseases to be controlled, however the final step

recites detection of the PCR products. Thus it cannot be determined if the goal of the preamble, i.e., "genotyping domestic fowl and enabling animals resistant to viro-induced diseases to be controlled", is achieved or not and if achieved, in what step it is achieved. Likewise, it cannot be clearly determined if the claims are intended to recited "a method genotyping..." or "a method of detecting a PCR product..". While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion (see *ex parte Erlich*, 3 UsPQ2d1011, p.1011 (Bd. Pat, Applicant. Int.1986). Clarification is required as to Applicant's intent.

(f) Claim 19 lacks proper antecedent basis for "the detection test" because no "detection test" has been recited or indicted in the method of claim 17. Likewise the claim is vague and confusing at "the necessary reagents" because no reagents, besides primers, have been identified by the method of claim of claim 17. Likewise, the specification does not define any reagents necessary or required for a kit. Clarification is required to Applicant's intent.

Conclusion

9. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Cynthia Wilder

CYNTHIA WILDER
PATENT EXAMINER
5/5/2005